

**PATENT**/Docket No. PC10901A

Appl. No. 09/779,413

Filing Date: February 8, 2001

Amdt. dated July 14, 2004

Reply to Office action of February 17, 2004

### REMARKS/ARGUMENTS

#### **Status of the Claims**

Claims 1-11 were pending as of the issuance of the instant Office Action. Claims 6, 10, and 11 have been amended. No new matter has been added as a result of the above-described amendments. The rejections set forth in the Office Action have been overcome by amendment or are traversed by argument below.

#### **Rejection of Claims under 35 USC §103**

Claims 1-11 stand rejected under 35 USC §103 as allegedly unpatentable over Harada et al., EP 0 882 719 (Harada '719) and Harada et al., WO 98/57938 (Harada '938). The Action alleges that Applicants fail to demonstrate that one skilled in the art would "ascertain a trend in the exemplified data that would allow him to reasonably extend the probative value thereof." Specifically, the Action alleges that the variable group "Ar" represents too many chemically different moieties that could not be seen as a trend by the skilled artisan. Applicants point out that the claims as presented (claims 1 and 10) or as amended (claim 6) recite that the "Ar" group can be a phenyl or a naphthyl group. Both phenyl and naphthyl are aromatic hydrocarbon groups, specifically aryl groups. Thus, one skilled in the art *would* recognize that the "Ar" groups are related. Consequently, a trend is readily ascertained from the demonstrated testing of the two compounds of the invention.

Also, the Action contends that "Applicants' genus includes a compound, i.e., the compound of Harada '938, Example 2, shown not to function in the manner claimed in all companion animals as presently claimed." Applicants point out that the compound of Harada '938, Example 2 is not in applicants' genus of claimed compounds. Specifically, the compound of Harada '938, Example 2 comprises a side chain that is not present on Formula I of the claimed invention. Formula I comprises a methoxide (-O-CH<sub>3</sub>) where the compound of Harada '938, Example 2 has -O-CH<sub>2</sub>-CH<sub>2</sub>-O-CH<sub>3</sub>. Consequently, Applicants contend that, absent evidence to the contrary, there is no expectation that a compound of the claimed genus of compositions will not work in a companion animal.

Furthermore, the Action asserts that companion animals encompass a diverse group of animals. On the contrary, the phrase "companion animals," as defined in the specification (see page 2, line 21, for example), includes animals that are disposed to endothelin-mediated disorders, particularly dogs, cats, and horses. One of skill in the art would reasonably expect the tests conducted in the Examples of the present application to apply, not only to dogs, but other companion animals, such as cats and horses, that express endothelin and are consequently susceptible to diseases associated with abnormal expression of endothelin.

Also, Claims 10-11 stand rejected as allegedly not containing a phrase that imparts any physical or otherwise material limitation to the claimed composition that is not found in the prior art compositions. Claims 10 and 11 have been amended to more particularly point out that the formulation of the invention is "suitable for oral administration to a companion animal." Support for the amendments can be found on pages 16-19 of the instant application where Applicants teach methods of administering

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and formulating pharmaceutical compositions of the invention, and specifically at page 19, lines 6-12, where Applicants describe suitable formulations for administration to companion animals. The prior art compositions are not formulated for use in companion animals. Thus, Applicants contend that the claims as amended are not obvious in view of the prior art compositions.

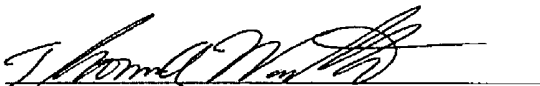
Therefore, Applicants contend that the two tested compounds of the invention are representative of the claimed genus, that the phrase "companion animals" encompasses dogs and reasonably extends to other companion animals that can have endothelin-mediated disorders, and the formulations of the invention are not found in the prior art. Applicants contend that the claims as originally presented and as amended are not obvious in view of the prior art references, and respectfully request that this ground of rejection be withdrawn.

#### CONCLUSION

In view of the remarks made above and the amendments presented herein, Applicants respectfully contend that all conditions of patentability are met in the pending claims as originally presented and as amended. Allowance of the claims is thereby respectfully solicited.

If there are any questions or comments regarding this Response or Application, the Examiner is encouraged to contact the undersigned attorney as indicated below.

Respectfully submitted,



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